

orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 12, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m., and between approximately 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 12, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the June 19, 2000, Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 1, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Technical Electronic Product Radiation Safety Standards Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Technical Electronic Product Radiation Safety Standards Advisory Committee.

General Function of the Committee: To provide advice on technical

feasibility, reasonableness, and practicality of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

Date and Time: The meeting will be held on June 21, 2000, 8:30 a.m. to 5 p.m., and June 22, 2000, 8:30 a.m. to 12 noon.

Location: Quality Suites, Potomac II and III, 3 Research Ct., Rockville, MD.

Contact Person: Orhan H. Suleiman, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12399. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 21, 2000, the committee will discuss: (1) A reproposal for amendments to the performance standard for lasers (part 1040 (21 CFR part 1040)), (2) amendments being considered for the sunlamps standard (part 1040), and hear (3) a presentation addressing nonmedical ionizing radiation security systems, (4) a presentation concerning computed tomography fluoroscopy (CT) and the Year 2000 Nationwide Evaluation of X-Ray Trends Survey of CT. On June 22, 2000, the committee will hear: (1) An update on the reengineering of the radiological health program at the Center for Devices and Radiological Health, (2) a presentation on manufacturers' requirements and the medical device approval process, and (3) a presentation regarding how ultrasound diathermy (21 CFR part 1050) is regulated by FDA.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 16, 2000. Oral presentations from the public will be scheduled on June 21, 2000, between approximately 11 a.m. and 11:20 a.m., and between approximately 1:45 p.m. and 2:05 p.m. Oral presentations from the public will be scheduled on June 22, 2000, between approximately 10:30 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 16, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the June 21, 2000, Technical Electronic Product Radiation Safety Standards Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Technical Electronic Product Radiation Safety Standards Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 1, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1267]

Draft "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated May 2000. The draft guidance document provides recommended questions for deferral of donors at increased risk for malaria. The guidance document also provides the recommendations for donor questioning regarding travel to vacation resorts located in malarious regions. The draft guidance document currently being announced, when finalized, will replace the recommendations in the guidance entitled "Recommendations for Deferral of Donors for Malaria Risk" dated July 26, 1994.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 6, 2000.

ADDRESSES: Submit written requests for single copies of "Guidance for Industry: Recommendations for Donor